

FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED)

ATTORNEY'S DOCKET NUMBER

X-16700B

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)

**10/535441**

INTERNATIONAL APPLICATION NO.

**PCT/US2003/038684**

INTERNATIONAL FILING DATE

**04 December 2003 (12.04.03)**

PRIORITY DATE CLAIMED

**04 December 2002 (12.04.02)**

**TITLE OF INVENTION: BUTYRYLCHOLINESTERASE VARIANTS THAT ALTER THE ACTIVITY OF  
CHEMOTHERAPEUTIC AGENTS**


**APPLICANT(S) FOR DO/EO/US: Jeffrey D. Watkins and James D. Pancook**

Applicant herewith submits to the U.S. Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A declaration of the inventors 35 U.S.C. 371(c)(4) was provided in the PCT Request Form.
11. ☐ A copy of the International Preliminary Examination Report (IPER), including any annexes, and, if not in English, an English language translation of the annexes to the IPER under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 12. to 18. below concern document(s) or information included:**

12. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
13. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☒ Assignment has been recorded at reel 014104, frame 0383, and recordation date 20 May 2003.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☒ A Sequence Listing, 1.821 Statement, and diskette.
18. ☒ A power of attorney and other documents.
18. ☒ Other items or information:  
Please amend the first page of the specification by inserting the following cross-reference after the title:  
"This is the national phase application, under 35 USC 371, for PCT/2003/038684, filed 04 December 2003, which claims the benefit, under 35 USC 119(e), of US application 10/310,666, filed 04 December 2002."

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5) <b>10/535441</b>		INTERNATIONAL APPLICATION NO. <b>PCT/US2003/038684</b>		ATTORNEY'S DOCKET NUMBER <b>X-16700B</b>																																																																											
19. <input checked="" type="checkbox"/> The following fees are submitted: Basic National Stage Fee = \$ 300.00  National Stage Search Fee = \$ 500.00  National Stage Examination Fee = \$ 200.00 <b>TOTAL NATIONAL STAGE FEES \$1,000.00 (a)</b>  Application Length Fee  Total Length (excluding sequence listings)  <u>121</u> - 100 = <u>21</u> excess pages (b)  No extra charge for first 100 pages. Must pay \$250 for each addl 50 pages (or fraction thereof).  <b>ENTER APPROPRIATE AMOUNT (a + b) =</b>				<b>CALCULATIONS PTO USE ONLY</b>																																																																											
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 1,250.00																																																																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">CLAIMS</th> <th style="width: 20%;">NUMBER FILED</th> <th style="width: 20%;">NUMBER EXTRA</th> <th style="width: 20%;">RATE</th> <th style="width: 20%;"></th> <th style="width: 20%;"></th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>46 - 20 =</td> <td>26</td> <td>X \$50.00</td> <td>\$ 1,300.00</td> <td></td> </tr> <tr> <td>Independent claims</td> <td>4 - 3 =</td> <td>1</td> <td>X \$200.00</td> <td>\$ 200.00</td> <td></td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+ \$360.00</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4"><b>TOTAL OF ABOVE CALCULATIONS =</b></td> <td>\$ 1,500.00</td> <td></td> </tr> <tr> <td colspan="4">Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4"><b>SUBTOTAL =</b></td> <td>\$ 1,250.00</td> <td></td> </tr> <tr> <td colspan="4">Processing fee of \$130.00 for furnishing English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4"><b>TOTAL NATIONAL FEE =</b></td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4">           Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).  <div style="text-align: right;">\$40.00 per property</div> </td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4"><b>TOTAL FEES ENCLOSED =</b></td> <td>\$ 2,750.00</td> <td></td> </tr> <tr> <td colspan="4" rowspan="2"></td> <td style="text-align: right;">Amount to be refunded</td> <td>\$</td> </tr> <tr> <td style="text-align: right;">charged</td> <td>\$</td> </tr> </tbody></table>				CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE			Total claims	46 - 20 =	26	X \$50.00	\$ 1,300.00		Independent claims	4 - 3 =	1	X \$200.00	\$ 200.00		MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00	\$		<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 1,500.00		Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$		<b>SUBTOTAL =</b>				\$ 1,250.00		Processing fee of \$130.00 for furnishing English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$		<b>TOTAL NATIONAL FEE =</b>				\$		Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <div style="text-align: right;">\$40.00 per property</div>				\$		<b>TOTAL FEES ENCLOSED =</b>				\$ 2,750.00						Amount to be refunded	\$	charged	\$		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE																																																																												
Total claims	46 - 20 =	26	X \$50.00	\$ 1,300.00																																																																											
Independent claims	4 - 3 =	1	X \$200.00	\$ 200.00																																																																											
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00	\$																																																																											
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 1,500.00																																																																											
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$																																																																											
<b>SUBTOTAL =</b>				\$ 1,250.00																																																																											
Processing fee of \$130.00 for furnishing English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$																																																																											
<b>TOTAL NATIONAL FEE =</b>				\$																																																																											
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <div style="text-align: right;">\$40.00 per property</div>				\$																																																																											
<b>TOTAL FEES ENCLOSED =</b>				\$ 2,750.00																																																																											
				Amount to be refunded	\$																																																																										
				charged	\$																																																																										
a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. 05-0840 in the amount of <u>\$2,750.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 05-0840. A duplicate copy of this sheet is enclosed.																																																																															
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>																																																																															
SEND ALL CORRESPONDENCE TO: ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, INDIANA 46206-6288  <u>May 19, 2005</u> Date <u>47,517</u> REGISTRATION NUMBER			<u>Paula K. Davis</u> SIGNATURE  <u>Paula K. Davis</u> NAME  <u>(317) 433-3422</u> TELEPHONE NUMBER		 <b>25885</b> PATENT TRADEMARK OFFICE																																																																										

10/535441

JC06 Rec'd PCT/PTO 19 MAY 2005  
Approved for use through 9/30/98, OMB 0651-0027  
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE**CERTIFICATE UNDER 37 CFR 3.73(b)**Applicant: Jeffrey Dean Watkins and James David PancookApplication No.: US Nat'l of PCT/US2003/038684 Filed: Int'l Filing Date 04 December 2003Entitled: BUTYRYLCHOLINESTERASE VARIANTS THAT ALTER THE ACTIVITY OF  
CHEMOTHERAPEUTIC AGENTSELI LILLY AND COMPANY, a CORPORATION

(Name of Assignee)

(Type of Assignee, e.g. corporation, partnership, university, government agency, etc.)

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application identified above.☒ The assignment was recorded in the Patent and Trademark Office at Reel 014104, Frame 0383.☐ The assignment is being submitted separately for recordation; a copy of this assignment is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.3. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.☐ Additional documents in the chain of title are listed on a supplemental sheet.☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

May 19, 2005  
DatePaula K. Davis  
Paula K. Davis  
Patent Attorney

10/535441 PCT  
JC06 Rec'd PCT/PTO 19 MAY 2005

**IN THE UNITED STATES RECEIVING OFFICE (USRO)**

Applicants: Jeffry Dean WATKINS and James David PANCOOK

International Application No.: PCT/US2003/038684

Filed: 04 December 2003 (12.04.03)

Invention: BUTYRYLCHOLINESTERASE VARIANTS THAT ALTER THE ACTIVITY OF  
CHEMOTHERAPEUTIC AGENTS

Lilly Reference: X-16700B

Earliest Priority Date: 04 December 2002 (12.04.02)

**Certificate Under 37 C.F.R. § 1.10**

Attention: DO/EO

Mail Stop PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir/Madam:

"Express Mail" mailing label number: EL832896444US

Date of Deposit: 19 May 2005

I hereby certify that the following attached paper or fee Transmittal Letter to the United States Designated/Elected Office (US) concerning a filing under 35 U.S.C. 371 of the International Application identified above is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Queen Thomas

(Typed or printed name of person mailing paper)

Queen Thomas

(Signature of person mailing paper or fee)